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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,148	02/26/2004	Shiu-Ru Lin	BHT/3230-85	8192

7590 07/02/2007
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FALLS CHURCH, VA 22041

EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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07/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,148

Applicant(s)

LIN ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 1,3 and 5-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election of invention 3, claims 2 and 4 and species HS 1526 in the reply filed on 4/12/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3 and 5-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/12/2007.

Status of Claims

Claims 1-79 are pending in the application.

Claims 1, 3 and 5-79 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 2 and 4 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 4 is objected to because the phrase "said gene sequences **are to a testing biochip** for detecting colorectal cancer" is grammatically incorrect.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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1. Claim 2 is unclear in claiming for a gene sequence but no sequence is recited by the HS ID No. and Acc. No. It is suggested that applicants positively recite the gene sequence to avoid any confusion.

2. Claim 4 is unclear whether the gene sequences are used for testing biochip? Clarification/Explanation is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertucci et al(20050287544). (Based on the claim (4) interpretation that the genes are present on a biochip).

Bertucci et al discloses in the abstract:

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Differential gene expression associated with histopathologic features of colorectal disease can be performed with nucleic acid arrays. Such arrays can comprise a pool of polynucleotide sequences from colon tissues, and the detection of the overexpression or underexpression of polynucleotide sequences (or subsequences or complements thereof) from this pool can provide information relating to the detection, diagnosis, stage, classification, monitoring, prediction, prevention or treatment of colorectal disease.

Bertucci et al discloses at paragraph:

[0009] DNA microarrays(biochip, as claimed) may be utilized to elucidate discrete gene sets to improve the prognostic classification of CRC, identify novel potential therapeutic targets of carcinogenesis, describe new diagnostic and/or prognostic markers, and guide physician decisions on appropriate patient care.

[0010] The invention thus provides a method for analyzing differential gene expression associated with histopathologic features of colorectal disease, comprising the detection of the overexpression or underexpression of a pool of polynucleotide sequences in colon tissues, said pool comprising all or part of the polynucleotide sequences, subsequences or complements thereof, selected from each of predefined polynucleotide sequence sets I through 644 set forth in Table 1.

[0011] ...The pool of polynucleotide sequences comprises all or part of the polynucleotide sequences, subsequences or complements thereof, selected from each of predefined polynucleotide sequence sets 1 through 644, as set forth in Table 1.

[0012] The invention further provides a polynucleotide library, comprising a pool of polynucleotide sequences either overexpressed or underexpressed in colon tissue, said pool corresponding to all or part of the polynucleotide sequences of **SEQ ID Nos. 1 through 1596**.

See further the Examples and claims.

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Eveleigh et al (20040146921).

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[0002] The present invention relates to gene expression profiles for colon cancer, microarrays (biochip, as in claim 4) comprising nucleic acid sequences representing gene expression profiles, and methods of using expression profiles and microarrays.

[0042] The terms "array" or "matrix" refer to an arrangement of addressable locations or "addresses" on a device. The locations can be arranged in two-dimensional arrays, three-dimensional arrays, or other matrix formats. The number of locations may range from several to at least hundreds of thousands. Most importantly, each location represents a totally independent reaction site. A "nucleic acid array" refers to an array containing nucleic acid probes, such as oligonucleotides or larger portions of genes. The nucleic acid on the array may be single-stranded. Arrays wherein the probes are oligonucleotides are referred to as "oligonucleotide arrays" or "oligonucleotide chips." A "microarray," also referred to herein as a "biochip" or "biological chip," is an array of regions having a density of discrete regions of, for example, at least about 100/cm², or at least about 1000/cm². The regions in a microarray have typical dimensions, for example, diameters, in the range of between about 10-250 μ m, and are separated from other regions in the array by about the same distance.

[0055] Tumors of the digestive tract include, but are not limited to, anal, colon, colorectal, esophageal, gallbladder, gastric, pancreatic, rectal, small-intestine, and salivary gland cancers.

See further the sequences of genes, Seq. ID. 1-191.

Claims 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al (WO 00155351).

Rosen discloses in the claims and sequences a gene that is used for diagnosing colorectal cancer. See also page 5, line 15 up to page 6, line 17. The colon cancer antigen with Sequence X is disclosed at page 8, lines 14-31. See also Table 1 as to the

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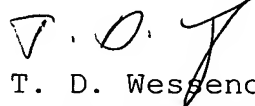
different gene sequences. Rosen at page 220, line 27 up to page 221, line 27 discloses a solid support(biochip, as claimed) to which the gene antigen is attached thereto.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
June 21, 2007